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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/781,723 | 02/20/2004 | Yuniko Shibata | 249169US0 | 4185 |

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C. IRVIN MCCLELLAND
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

| EXAMINER | |
|---|---|
| HENRY, MICHAEL C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/781,723 | SHIBATA, YUNIKO | |
| | Examiner | Art Unit | |
| | Michael C. Henry | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The following office action is a responsive to the Amendment filed, 04/03/06.

The amendment filed 04/03/06 affects the application, 10/781,723 as follows:

1. Claims 6, 9, 10 have been amended. Claims 1 and 2 have been previously canceled. This leaves claims 3-10. It should be noted that claims 9 and 10 have also been amended (even though these claims are not indicated as been currently amended) by applicant, since claims 9 and 10 now recite "according to claim 4" instead of "according to claim 6" as recited in the previously examined claims.
2. The responsive to applicants' arguments is contained herein below.

Claims 3-10 are pending in application

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs et al. (Radiation Research (1959), vol.11, pages 149-64).

In claim 6, applicant claims "A method for producing a purified low molecular weight glycosaminoglycan, having a molecular weight of 200 to 1,000,00 Da, which comprises irradiating a crude glycosaminoglycan containing ultraviolet ray-absorbing contaminants, comprising at least one of proteins, nucleic acids, and pigments, with an ultraviolet ray to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the

contaminants. Balazs et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (hyaluronic acid), which comprises irradiating the glycosaminoglycan (hyaluronic acid) with an ultraviolet ray (ultraviolet light) to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants (see abstract). Balazs discloses that the low molecular weight glycosaminoglycan, has a molecular weight of 19,700 Da (see page 162, 2nd paragraph). The examiner considers Balazs et al.'s method one which also comprises the simultaneous decomposition and removal the contaminants, since Balazs et al. produces low molecular weight glycosaminoglycan by irradiating the same glycosaminoglycan (hyaluronic acid) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition and removal of the contaminants occurs simultaneously as the low molecular weight glycosaminoglycan is produced by irradiation. Moreover, Balazs et al.' disclose that the hyaluronic acid preparations of their experiments are from human umbilical cord and bovine vitreous body and that these hyaluronic acid preparations do contain a protein content of less than 5% (see Material and Methods, page 149). Consequently, the Balazs et al.'s method must comprise the simultaneous decomposition and removal of the said protein (contaminants). Claim 3, which is drawn to the method according to claim 6, wherein the glycosaminoglycan is selected from the group consisting of hyaluronic acid, chondroitin, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate and keratin sulfate, is anticipated by Balazs et al., since Balazs et al. use the glycosaminoglycan, hyaluronic acid (see abstract). In claim 4, applicant claims "The method according to claim 6, wherein temperature is maintained at 1 to 37°C during ultraviolet ray irradiation. Balazs et al. disclose applicant's method of claim 4, since Balazs et al. disclose that

the temperature was kept < 37 °C or < 35°C (see page 150, last paragraph). Claim 8 is drawn to a method of claim 4, wherein said temperature is maintained at 10 to 25°C during ultraviolet ray irradiation. Balazs et al. disclose applicant's method of claim 8, since Balazs et al. disclose that the temperature was kept < 37 °C or < 35°C (see page 150, last paragraph). The examiner considers Balazs et al.'s method one which also comprises the simultaneous decomposition and removal the contaminants, since Balazs et al. produces the same low molecular weight glycosaminoglycan by irradiating the same glycosaminoglycan (hyaluronic acid) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition and removal of the contaminants occurs simultaneously as the low molecular weight glycosaminoglycan is produced by irradiation. Moreover, Balazs et al. disclose that the hyaluronic acid preparations of their experiments are from human umbilical cord and bovine vitreous body and that these hyaluronic acid preparations do contain a protein content of less than 5% (see Material and Methods, page 149). Consequently, the Balazs et al.'s method must comprise the simultaneous decomposition and removal the said protein (contaminants). Claim 5, which is drawn to a method of claim 6, wherein the ultraviolet ray has a wavelength of 250 to 450 nm, is anticipated by Balazs et al., since Balazs et al.'s hyaluronic acid product is formed with a maximum wave length at 2670 Å (267 nm) (see abstract). Claims 9 and 10 which are drawn to the method according to claim 4 wherein the low molecular weight glycosaminoglycan is of specific molecular weight, are also anticipated by Balazs et al., since Balazs et al's glycosaminoglycan (hyaluronic acid) has the same molecular weight (19,700) as applicant's glycosaminoglycan (see page 162, 2$^{nd}$ paragraph). The examiner considers Balazs et al.'s method one which also comprises the simultaneous decomposition and removal the

contaminants, since Balazs et al. produces the same low molecular weight glycosaminoglycan by irradiating the same glycosaminoglycan (hyaluronic acid) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition and removal of the contaminants occurs simultaneously as the low molecular weight glycosaminoglycan is produced by irradiation. Moreover, Balazs et al. disclose that the hyaluronic acid preparations of their experiments are from human umbilical cord and bovine vitreous body and that these hyaluronic acid preparations do contain a protein content of less than 5% (see Material and Methods, page 149). Consequently, the Balazs et al.'s method must comprise the simultaneous decomposition and removal the said protein (contaminants).

Claims 3, 5, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hvidberg et al. (Acta Pharmacologica et Toxicologica (1959), 15, 356-64).

In claim 6, applicant claims "A method for producing a purified low molecular weight glycosaminoglycan, having a molecular weight of 200 to 1,000,00 Da, which comprises irradiating a crude glycosaminoglycan containing ultraviolet ray-absorbing contaminants, comprising at least one of proteins, nucleic acids, and pigments, with an ultraviolet ray to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants. Hvidberg et al. disclose applicant's method of producing a low molecular weight glycosaminoglycan (hyaluronic acid), which comprises irradiating the glycosaminoglycan (hyaluronic acid) with an ultraviolet ray (ultraviolet light) to lower the molecular weight of the glycosaminoglycan and simultaneously decompose and remove the contaminants (see abstract). Hvidberg et al. disclose that the molecular weight hyaluronic acid products were about 1000 (see abstract). The examiner considers Hvidberg et al.'s method one which also comprises the

simultaneous decomposition and removal the contaminants, since Hvidberg et al. produces low molecular weight glycosaminoglycan of the same low molecular weight (about 1000) by irradiating the same glycosaminoglycan (hyaluronic acid) as applicant with the same ultraviolet ray (ultraviolet light) of same wavelength. It should be noted that applicant's claimed decomposition and removal of the contaminants occurs simultaneously as the low molecular weight glycosaminoglycan is produced by irradiation. Furthermore, it should be noted that Hvidberg et al.'s hyaluronic acid was prepared from umbilical cords which are known to contain protein and nucleic acid as contaminants (for example, see Shiedlin et al., Biomacromolecules 2004, Vol. 5, 2122-2127, especially the abstract; table 1, page 2123; and conclusion, page 2127). Consequently, the examiner considers Hvidberg et al.'s hyaluronic acid from umbilical cords one that inherently contains proteins and nucleic acid although Hvidberg et al. is silent about these contaminants. Claim 3, which is drawn to the method according to claim 6, wherein the glycosaminoglycan is selected from the group consisting of hyaluronic acid, chondroitin, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate and keratin sulfate, is anticipated by Hvidberg et al., since Hvidberg et al. use the glycosaminoglycan, hyaluronic acid (see abstract). Claim 5, which is drawn to a method of claim 6, wherein the ultraviolet ray has a wavelength of 250 to 450 nm, is anticipated by Hvidberg et al., since Hvidberg et al.'s hyaluronic acid product use light of wave length at 2550 Å (255 nm) (see abstract).

***Response to Amendment***

Applicant's arguments with respect to claims 3-10 have been considered but are not found convincing.

The applicant argues that neither Balazs et al. nor Hvidberg et al. specifically disclose or suggest such decomposition and removal of contaminants, especially decomposition and removal of the contaminants specifically defined in claim 6 amended above (i.e., contaminants, comprising at least one of proteins, nucleic acids, and pigments). However, both Balazs et al. and Hvidberg et al. disclose the irradiation of the same glycosaminoglycan (hyaluronic acid) (containing the same protein and nucleic acid contaminants) with the same ultraviolet ray to produce the same low molecular weight glycosaminoglycan (hyaluronic acid). This implies that both Balazs et al. and Hvidberg et al. method must also simultaneously decompose and remove the contaminants (as claimed by applicant), especially since there is no different step or limitation claimed by applicant that renders applicant's method different from Balazs et al.'s and Hvidberg et al.'s method.

The applicant argues that neither Balazes et al nor Hvidberg et al specifically disclose or suggest the same when simultaneously attained by ultraviolet irradiation with lowering the molecular weight of the glycosaminoglycan as claimed by the present invention. However, both Balazs et al. and Hvidberg et al. disclose the irradiation of the same glycosaminoglycan (hyaluronic acid) (containing the same protein and nucleic acid contaminants) with the same ultraviolet ray to produce the same low molecular weight glycosaminoglycan (hyaluronic acid). This implies that both Balazs et al. and Hvidberg et al. method must also simultaneously decompose and remove the contaminants (as claimed by applicant), especially since there is no different step or limitation claimed by applicant that renders applicant's method different from Balazs et al.'s and Hvidberg et al.'s method.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

July 19, 2006.